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 Counterclaim-Plaintiff SEQUENOM, INC.

**UNITED STATES DISTRICT COURT  
 FOR THE NORTHERN DISTRICT OF CALIFORNIA**

NATERA, INC.,

Plaintiff,

v.

SEQUENOM, INC. and  
 ISIS INNOVATION LIMITED

Defendants.

Case No. 5:12-cv-00132-SI

**ANSWER AND COUNTERCLAIMS OF  
 DEFENDANT AND COUNTERCLAIM-  
 PLAINTIFF SEQUENOM, INC.**

**DEMAND FOR JURY TRIAL**

SEQUENOM, INC.

Counterclaim-Plaintiff,

v.

NATERA, INC. and  
 DNA DIAGNOSTICS CENTER, INC.

Counterclaim-Defendants,

and

ISIS INNOVATION LIMITED,

Nominal Counterclaim-  
 Defendant.

**ANSWER**

Defendant and Counterclaim-Plaintiff Sequenom, Inc. ("Sequenom"), by and through its undersigned attorneys, for its answer to the First Amended Complaint ("Complaint") of Natera, Inc. ("Natera"), and for its counterclaims, alleges, on knowledge as to itself and on information and belief as to other matters, as follows:

1. Paragraph 1 of the Complaint alleges Natera's purported purpose in filing this action, to which no response is required. To the extent a response is required, Sequenom denies the allegations of paragraph 1 of the Complaint and that Natera has any cognizable basis for filing the present action. Sequenom admits that Exhibit A to the Complaint appears to be a copy of U.S. Patent Number 6,258,540 ("the '540 patent"), but Sequenom has not verified that it is a true and correct copy in all respects.

2. Sequenom admits, upon information and belief, the allegations of paragraph 2 of the Complaint.

3. Sequenom admits the allegations of paragraph 3 of the Complaint.

4. Sequenom admits, upon information and belief, the allegations of paragraph 4 of the Complaint.

5. Paragraph 5 of the Complaint alleges legal conclusions to which no response is required. To the extent a response is required, Sequenom denies the allegations of paragraph 5 of the Complaint.

6. Sequenom admits that this Court has jurisdiction over federal questions pursuant to 28 U.S.C. § 1331 and over civil actions arising under the Patent Act pursuant to 28 U.S.C. § 1338. Except as so admitted, Sequenom denies the allegations of paragraph 6 of the Complaint.

7. Sequenom admits that it is subject to personal jurisdiction in this District and venue is proper in this District pursuant to 28 U.S.C. § 1391(c). Except as so admitted, Sequenom denies the allegations of paragraph 7 of the Complaint.

8. Sequenom admits that this action is properly assigned to any Division in this District pursuant to Civil Local Rule 3-2(c). Except as so admitted, Sequenom denies the allegations of paragraph 8 of the Complaint.

9. Sequenom admits that Natera has represented that “Natera’s Non-Invasive Paternity Test is intended to confirm the paternity or non-paternity of a gestating fetus from genetic information in fetal DNA available in the blood of the pregnant mother.” Except as so admitted, Sequenom is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 9 of the Complaint and on that basis denies those allegations.

10. Sequenom is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10 of the Complaint and on that basis denies those allegations.

11. Sequenom is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the Complaint and on that basis denies those allegations.

12. Sequenom is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 12 of the Complaint and on that basis denies those allegations.

13. Sequenom admits that Natera has represented that “Natera began offering its Non-Invasive Paternity Test on or about August 2011. As of the date of this filing, Natera and its licensees continue to offer the test.” Except as so admitted, Sequenom is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint and on that basis denies those allegations.

14. Sequenom admits the allegations of paragraph 14 of the Complaint.

15. Sequenom admits that on or about December 6, 2011, its outside counsel sent a letter to Gene Security Network’s (now Natera’s) Chief Executive Officer, Dr. Matthew Rabinowitz, regarding the ’540 patent, and that Sequenom’s letter speaks for itself. Except as so admitted, Sequenom denies the allegations of paragraph 15 of the Complaint.

16. On information and belief, Sequenom admits the allegations of paragraph 16 of the Complaint.

1           17.     Sequenom admits that Dr. Dereck Tatman is Vice President of Business  
2 Development of Sequenom. Except as so admitted, Sequenom denies the allegations of paragraph  
3 17 of the Complaint.

4           18.     Sequenom admits that on or about August 22, 2011, Dr. Tatman sent an email to  
5 Dr. Rabinowitz, and that such email speaks for itself. Except as so admitted, Sequenom denies the  
6 allegations of paragraph 18 of the Complaint.

7           19.     Sequenom admits that on or about August 23, 2011, Dr. Rabinowitz sent an email to  
8 Dr. Tatman. Except as so admitted, Sequenom denies the allegations of paragraph 19 of the  
9 Complaint.

10          20.     Sequenom admits that on or about December 6, 2011, its outside counsel sent a  
11 letter to Gene Security Network's (now Natera's) Chief Executive Officer, Dr. Matthew  
12 Rabinowitz, regarding the '540 patent, and that Sequenom's letter speaks for itself. Sequenom  
13 further admits that Michael Malecek is a partner of Kaye Scholer LLP and that his website  
14 biography states that he is a partner in the Intellectual Property Litigation and the White Collar  
15 Litigation and Internal Investigations practice groups. Except as so admitted, Sequenom denies the  
16 allegations of paragraph 20 of the Complaint.

17          21.     Sequenom admits that on or about December 6, 2011, its outside counsel sent a  
18 letter to Gene Security Network's (now Natera's) Chief Executive Officer, Dr. Matthew  
19 Rabinowitz, regarding the '540 patent, and that Sequenom's letter speaks for itself. Except as so  
20 admitted, Sequenom denies the allegations of paragraph 21 of the Complaint.

21          22.     Sequenom admits that on or about January 4, 2012, Dr. Tatman sent an email to  
22 Dr. Rabinowitz, and that such email speaks for itself. Except as so admitted, Sequenom denies the  
23 allegations of paragraph 22 of the Complaint.

24          23.     Sequenom admits that any email Dr. Tatman sent to Mr. Vitulli speaks for itself.  
25 Except as so admitted, Sequenom denies the allegations of paragraph 23 of the Complaint.

26          24.     Sequenom admits that on or about December 6, 2011, its outside counsel sent a  
27 letter to the DNA Diagnostics Center's President and Chief Executive Officer, Mr. Peter Vitulli,  
28

1 regarding the '540 patent, and that Sequenom's letter speaks for itself. Except as so admitted,  
2 Sequenom denies the allegations of paragraph 24 of the Complaint.

3 25. As its Answer to paragraph 25 of the Complaint, Sequenom repeats and re-alleges  
4 the allegations set forth in paragraphs 1 through 24 above of Sequenom's Answer.

5 26. Paragraph 26 of the Complaint alleges legal conclusions to which no response is  
6 required. To the extent a response is required, Sequenom denies the allegations of paragraph 26 of  
7 the Complaint.

8 27. Sequenom denies the allegations of paragraph 27 of the Complaint.

9 28. As its Answer to paragraph 28 of the Complaint, Sequenom repeats and re-alleges  
10 the allegations set forth in paragraphs 1 through 27 above of Sequenom's Answer.

11 29. Paragraph 29 of the Complaint alleges legal conclusions to which no response is  
12 required. To the extent a response is required, Sequenom denies the allegations of paragraph 29 of  
13 the Complaint.

14 30. Sequenom denies the allegations of paragraph 30 of the Complaint.

15 31. As to Natera's Prayer for Relief and paragraphs A to F thereof, Sequenom denies  
16 that Natera is entitled to the relief it seeks or any relief.

### 17 **AFFIRMATIVE DEFENSES**

18 As and for its affirmative defenses in the above-captioned action, Sequenom hereby states  
19 and alleges:

#### 20 **First Affirmative Defense (Failure To State A Claim)**

21 32. The Complaint fails to state a claim upon which relief can be granted.

#### 22 **Second Affirmative Defense (Infringement of the '540 Patent)**

23 33. Natera's past, current, and planned activities, as alleged in the Complaint and as  
24 alleged by Sequenom in its counterclaims, have infringed and do and will infringe the '540 patent.

#### 25 **Third Affirmative Defense (Equitable Defenses)**

26 34. Natera's claim for declaratory judgment is barred, in whole or in part, by the  
27 equitable doctrines of estoppel, waiver, and/or unclean hands.

**Fourth Affirmative Defense**

35. Sequenom reserves the right to plead other affirmative defenses that might arise during the course of this litigation.

**COUNTERCLAIMS OF**

**DEFENDANT AND COUNTERCLAIM-PLAINTIFF SEQUENOM, INC.**

Defendant and Counterclaim-Plaintiff Sequenom, Inc. (“Sequenom”) upon knowledge as to its own acts and upon information and belief as to the actions of Plaintiff and Counterclaim-Defendant Natera, Inc. (“Natera”), Counterclaim-Defendant DNA Diagnostics Center, Inc. (“DDC”), and Nominal Counterclaim-Defendant Isis Innovation Limited (“Isis”) and others, by its attorneys, alleges as follows:

**NATURE OF THE ACTION**

1. This is an action under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, for infringement by Natera and DDC of United States Patent No. 6,258,540 (hereinafter referred to as the ’540 patent”), which is exclusively licensed by Sequenom from Isis.

**THE PARTIES**

2. Sequenom is a Delaware corporation with its principal place of business at 3595 John Hopkins Court, San Diego, California 92121.

3. On information and belief, Defendant Natera is a corporation incorporated under the laws of the state of Delaware with a principal place of business at 2686 Middlefield Road, Redwood City, California 94063.

4. On information and belief, Natera uses, offers for sale and/or sells its infringing processes in this Judicial District, among other places.

5. On information and belief, Defendant DDC is a corporation incorporated under the laws of the state of Ohio with a principal place of business at One DDC Way Fairfield, Ohio 45014.

6. On information and belief, DDC offers for sale and/or sells its infringing processes in this Judicial District, among other places.

7. Nominal Counterclaim-Defendant Isis is a British company whose registered office is at University Offices, Wellington Square, Oxford OX1 2JD, England. Isis is named as a nominal counterclaim-defendant in this action for purposes of subject matter jurisdiction only and pursuant to the United States Supreme Court's holding in *Independent Wireless Tel. Co. v. Radio Corp. of Am.*, 269, U.S. 459, 468 (1926), that "[i]f the owner of a patent, being within the jurisdiction, refuses or is unable to join an exclusive licensee as coplaintiff, the licensee may make him a party defendant by process, and he will be lined up by the court in the party character which he should assume." Sequenom requested that Isis join as a party in this action, but Isis has thus far not agreed to do so. Although Isis is named as a nominal counterclaim-defendant, Sequenom seeks relief realigning Isis as a co-counterclaim-plaintiff.

#### **JURISDICTION AND VENUE**

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Natera because Natera's principal place of business is within the District and it has purposely availed itself of the privilege of conducting activities within this State and District, including filing the above-captioned action.

10. This Court has personal jurisdiction over DDC because DDC conducts business in the State of California and it has purposely availed itself of the privilege of conducting activities within this State and District.

11. This Court has personal jurisdiction over Isis because Isis has purposely availed itself of the privilege of conducting activities within this State and District.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§1391(b) and (c), and 1400(b).

#### **THE PATENT-IN-SUIT**

13. Sequenom is the exclusive licensee of the '540 patent, duly and legally issued on July 10, 2001 to the named assignee Isis, entitled "Non Invasive Prenatal Diagnosis." A true and correct copy of the '540 patent is attached to this Answer and Counterclaims as Exhibit 1.

14. The claims of the '540 patent relate to nucleic acid analysis and prenatal diagnosis.

15. Sequenom is a pioneer in bringing non-invasive prenatal testing to market. For example, in 2011, Sequenom was the first company to market a non-invasive prenatal diagnostic test for Down Syndrome, MaterniT21™.

### **ACCUSED INFRINGERS**

16. On information and belief, Natera, founded in 2004 and previously known as Gene Security Network, Inc., operates a laboratory in Redwood City, California and offers services including non-invasive prenatal paternity testing to determine paternity and non-invasive prenatal aneuploidy testing by analyzing cell-free fragments of fetal DNA in a pregnant mother's blood drawn during pregnancy.

17. Natera's website states, among other things, that "Natera now provides non-invasive prenatal paternity testing."

18. Natera is also offering on an investigational basis non-invasive aneuploidy testing. Natera's website refers to several clinical trials and states: "PreNATUS (Prenatal Non-invasive Aneuploidy Testing Using SNPs) - This is a prospective blinded trial to validate clinical use of Parental Support™ technology to detect genetic abnormalities (including Down Syndrome) from free floating fetal DNA found in maternal blood during pregnancy."

19. Natera's website further states: "Non-invasive Prenatal Diagnosis Validation - This is a retrospective trial to validate use of Parental Support technology to detect a broad group of chromosome abnormalities (including microdeletions) from free floating fetal DNA found in maternal blood during pregnancy. This study is actively recruiting patients that are carrying a fetus diagnosed with any chromosome abnormality by amniocentesis or CVS. Patients can participate by contacting Natera directly at info@natera.com."

20. On information and belief, Natera's non-invasive prenatal paternity testing and non-invasive prenatal aneuploidy testing use the methods claimed in the '540 patent.



1           21. On information and belief, Natera is using, selling, and/or offering for sale its non-  
2       invasive prenatal paternity testing and non-invasive prenatal aneuploidy testing in the United  
3       States, including this District.

4           22. On information and belief, Natera has also knowingly encouraged others, including  
5       DDC, to use Natera's non-invasive prenatal paternity testing methods. For example, on  
6       information and belief, Natera has knowingly encouraged DDC to perform non-invasive prenatal  
7       paternity testing to determine paternity by analyzing cell-free fragments of fetal DNA in a pregnant  
8       mother's blood drawn during pregnancy, using methods claimed in the '540 patent. For example,  
9       Natera's website states: "If you are a patient seeking non-invasive paternity testing please contact  
10      the appropriate partner below. ...For the U.S. and Canada:  
11      <http://www.dnacenter.com/paternity/prenatal-testing.html>." On information and belief,  
12      www.dnacenter.com is DDC's website.

13          23. On information and belief, DDC offers paternity testing services and has partnered  
14      with Natera to offer a non-invasive prenatal paternity test. For example, a DDC press release dated  
15      August 16, 2011, states that "DNA Diagnostics Center (DDC) the largest provider of private DNA  
16      paternity and other DNA tests in the United States and around the world, announced today the  
17      company's exclusive license in the US for the first non-invasive prenatal paternity test using SNP  
18      (single-nucleotide polymorphism) Microarray Technology, which requires only a simple blood  
19      draw from the mother and alleged father." The press release further states that DDC secured "the  
20      exclusive license from Gene Security Network (GSN) [*i.e.*, Natera]."

21          24. On information and belief, DDC's non-invasive prenatal paternity testing uses the  
22      methods claimed in the '540 patent.

23          25. On information and belief, DDC is using, selling, and/or offering for sale its non-  
24      invasive prenatal paternity testing in the United States, including this District.

**COUNT 1****(Infringement of United States Patent No. 6,258,540 by Natera)**

26. Sequenom realleges and incorporates herein by reference the allegations stated in paragraphs 1-35 of Sequenom's Answer and paragraphs 1-25 of these Counterclaims.

27. Natera has been and still is directly infringing the '540 patent by using, offering for sale, and/or selling in the United States its non-invasive prenatal paternity testing and its non-invasive prenatal aneuploidy testing.

28. Natera has been and still is indirectly infringing the '540 patent by knowingly encouraging others to use, offer for sale, and/or sell in the United States its non-invasive prenatal paternity testing and/or its non-invasive prenatal aneuploidy testing.

29. On information and belief, Natera's infringement of the '540 patent has taken place with full knowledge of the '540 patent and has been intentional, deliberate, and willful.

30. On information and belief, Natera will continue to infringe the '540 patent unless and until it is enjoined by this Court.

**COUNT 2****(Infringement of United States Patent No. 6,258,540 by DDC)**

31. Sequenom realleges and incorporates herein by reference the allegations stated in paragraphs 1-35 of Sequenom's Answer and paragraphs 1-30 of these Counterclaims.

32. DDC has been and still is directly infringing the '540 patent by using, offering for sale, and/or selling in the United States non-invasive prenatal paternity testing.

33. On information and belief, DDC's infringement of the '540 patent has taken place with full knowledge of the '540 patent and has been intentional, deliberate, and willful.

34. On information and belief, DDC will continue to infringe the '540 patent unless and until it is enjoined by this Court.

**PRAYER FOR RELIEF**

WHEREFORE, Sequenom prays that this Court:

- A. Deny Natera's request for declaratory relief;
- B. Enter a judgment that each of Natera and DDC has infringed the '540 patent;
- C. Grant injunctive relief restraining and enjoining Natera and DDC, their officers, directors, agents, servants, employees, successors, assigns, parents, subsidiaries, affiliated or related companies, and attorneys, and all those acting in concert or participating with them from making, using, selling, offering for sale, or importing into the United States any product or service, including without limitation Natera's non-invasive prenatal paternity testing and non-invasive prenatal aneuploidy testing, utilizing the methods of any claim of the '540 patent;
- D. Award Sequenom damages in an amount sufficient to compensate Sequenom for Natera's and DDC's infringement of the '540 patent, but not less than a reasonable royalty, including pre- and post-verdict supplemental damages;
- E. Award prejudgment interest to Sequenom pursuant to 35 U.S.C. § 284;
- F. Award increased damages, pursuant to 35 U.S.C. § 284, in an amount not less than three times the amount of actual damages awarded to Sequenom, by reason of Natera's and DDC's willful infringement of the '540 patent;
- G. Declare this case exceptional under 35 U.S.C. § 285 and award Sequenom its reasonable attorneys' fees, expenses, and costs incurred in this action; and
- H. Grant such other and further relief as this Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6(a), Sequenom hereby demands a trial by jury on all issues so triable.

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1 DATED: April 18, 2012

3 /s/ Michael J. Malecek

4 Michael J. Malecek

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